REMARKS

The rejection of Claims 4, 11, 34, 37-38 and 41 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is respectfully traversed.

The Examiner has alleged that the Claims contain subject matter not described in the specification in such a way as to enable one skilled in the art to which it pertains or to which it is most nearly connected to make and/or use the invention. Applicant respectfully believes the Examiner misunderstands the invention which is clearly enabling to one skilled in the art. Claim 11 has been further amended to overcome the misunderstanding of the Examiner. In Step (1) of Claim 11, a sample containing virus is treated with an ionic surfactant and other reagent to liberate viral proteins and to inactivate antibodies to the viral protein. In Step (2) the liberated viral proteins are detected with an antibody to the viral protein. Step 1 of the subject invention causes endogenous antibodies to be inactivated by an anionic surfactant and other reagent such as e.g. a nonionic surfactant contained in a treatment solution. In this step, the anionic surfactant and other reagent in the treatment solution are consumed by binding to viruses and endogenous antibodies to the viruses. It should be understood that a biological sample contains a large amount of proteins such as antibodies, albumin, etc. for example, blood contains about 100mg/ml proteins and 1g of protein binds about 1.4 g SDS which is an anionic surfactant. Therefore, most of the anionic surfactant and other reagent in the treatment solution are consumed during the first step of Claim 11.

In addition the biological samples treated in Step 1 is reacted with a reagent buffer. As a result remaining ionic surfactant and other reagent are diluted. The reaction buffer contains a significant amount of proteins such as bovine serum, albumin, casein, etc. which function to inhibit non-specific reactions. Therefore, the remaining ionic surfactant and other reagent are consumed by binding to these proteins in the second step.

By consuming the ionic surfactant and other reagent, at the time of detection, a reagent antibody will not be inactivated and remains available for detection.

In summary, the present invention is completed upon treatment of the biological sample with the treatment solution and carrying our the detection using a reagent buffer and a reagent monoclonal antibody. In fact, an antigen of HCV and HBV can be detected by the above steps with high sensitivity. Claim 11, as amended claim makes it clear that upon treatment of the virus containing sample as claims the virus particle is disrupted, the virus antigen exposed or released and antibodies against the virus antigen, if present in the sample, are inactivated.

The Examiner alleges that "the recited claims and specification provide no guidance as to the volume of the 'reaction buffer' used or the threshold concentrations of the treatment solution components below which they will no longer denature proteins." To the contrary, the volume of the reaction buffer needed for immune reaction would be known to those skilled in the art and is conventional and a specific or nonconventional volume is not necessary for use in the present invention. In addition, it is well known to those skilled in the art that a reaction buffer contains a significant amount of protein and that this is conventional for protection and maintenance of sensitivity of the monoclonal antibody. Accordingly Applicant's method relies on what is well known to those skilled in the art in carrying out the method. This does not have to be expressly included in the specification since one skilled in the art needs no guidance as to the volume of reaction buffer and needs no guidance as to the special concentration of the treatment solution. If the Examiner prefers applicant is willing to submit a declaration under 132 attesting to this rule.

Based upon the Examiner's misunderstanding of the invention and his assumption as to what is missing from the specification and Claims the Examiner has stated that "therefore, since the specification gives no guidance as to what combination of components (and at what concentration), if any, would result in a treatment solution that would inactivate the endogenous antibodies present in the biological sample (Step 2 of the claimed method) but not inactivate the antibody probe subsequently used in the

immunoassay (Step 3 of the claimed method), the specification is not enabling for the claimed method."

The Examiner should recognize that the end product of Step(1) is the starting material for Step (2). This is self evident from the teaching in the specification and claims. Accordingly the rejection of Claims 11, 37 and 41 based on the allegations that steps 1 and 2 are not linked together by claim language has no merit and should be withdrawn.

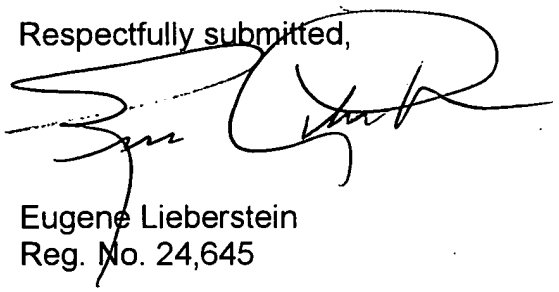
In addition, the Examiner has stated that "Claims 11, 37 and 41 are rendered vague and indefinite by the use of the phrase "reaction buffer" since this term is not explicitly defined in the specification. To the contrary the "reaction buffer" is described in the specification in Example 4 on page 39, line 31 as "100mM sodium phosphate buffer, pH 7.3 containing 0.15M NaCl, 1% BSA, 0.5% casein Na and 0.05% Tween 20"; Example 5 on page 41, line 41 as "120ul of the reaction buffer . . ."; in Example 14, on page 53, line 3 as "and 200ul of the reaction solution . . ."; and in Example 14 on page 53, line 14 as "a well filled with the reaction solution, and was . . ." The above teaching in the specification describes clearly the reaction buffer or reaction solution to any one skilled in the art as a medium for the treated biological sample and the reagent monoclonal antibody for detection. The composition of the reaction buffer is conventional and does not require any further specificity.

Although this rejection has been made Final it is based solely upon rejections under 35 USC 112 and applicant has further amended claim 11 to place the application in condition for allowance or in the alternative to clarify any misunderstanding for purpose of appeals. Should the Examiner still refuse to allow the application, enclosed herewith is a Notice of Appeal. The requisite fee should be deduced from our deposit account number 01-1944.

Reconsideration allowance of Claim 4, 11, 34, 37-38 and 41 is respectfully solicited.

Reconsideration allowance of Claim 4, 11, 34, 37-38 and 41 is respectfully solicited.

Respectfully submitted,

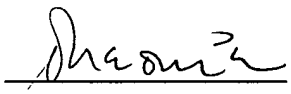


Eugene Lieberstein
Reg. No. 24,645

ANDERSON, KILL & OLICK
1251 Avenue of the Americas
New York, New York 10020-1182
(212) 278-1000

MAILING CERTIFICATE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 14, 2004.



Date: March 14, 2004